Appendix F. Compliance with PCORI Methods Standards

• **Summary of Compliance with Methodology Standards**	
• **1: Standard for Formulating Research Questions**	• In the development of our proposal and execution of our project we conformed to the PCORI's methodology standards by implementing the following activities: 1) reviewing the literature at several points in time to around issue related to lay health workers roles and the measurement of clinic-community linkages (RA-1), 2) Proposing and documenting a specific mixed methods study protocol (RA-2), 3) working closely with our health system to identity appropriate clinics and populations for the intervention, working with patients to design a role aimed at addressing community resource needs and carefully monitoring and evaluating the implementation of the intervention (RQ-3, RQ-4, RQ-5, RQ-6). We also engaged stakeholders • in an ongoing way to ensure that the project was answering relevant questions.
• **2: Standards Associated with Patient-Centeredness**	• Our study conformed to the PCORI's methodology standards by implementing the following activities: 1) Engaging two patient co-investigators who participated in standing science team meetings, ad hoc activities and dissemination of findings (PC-1, PC-4), 2) Engaging 12 patients to participate in co-designing the intervention (PC-1 PC-2), 3) Engaging community advisory panels to provide stakeholder input and assist with dissemination activities (PC-1, PC-4), 4) Recruiting study participants that represented the spectrum of the • population of interest for focus groups and survey administration (PC-2, PC-3).
• **3: Standards for Data Integrity and Rigorous Analyses**	• For this standard, we reference our proposal, Section C.2. Analytic Methods and • • C.1.e. Choice of Outcomes, and our Study Protocol (IR-2, IR-3, and IR-4). For each of our data sources, the project team has experts which have worked with these types of data for years and know the strengths and limitations of each source. • We conducted analyses appropriate for each source of data. For survey analyses as

•	• well as abstracted data around CRS activities, we a priori chose to not make any formal statistical tests due to sample size constraints, and instead report the direct responses of the participants (IR-3). For the analysis of healthcare utilization and measurement of patient vitals (such as HbA1c), we conducted matched cohort analyses, comparing patients who utilized the CRS program to demographically-similar patients at a different clinic (IR-2). Unfortunately, our matching process did not produce a comparable matched cohort for patient vitals, so we • chose not to perform statistical tests on those measures (IR-5).
• **4: Standards for Preventing and Handling Missing Data**	• This standard is relevant primarily for survey and quantitative data analyses. We reference our proposal, section C.2.a. There were no missing data in the healthcare utilization data, or in the CRS activity data. For patients who were missing monthly vitals data (such as HbA1c), we conducted multiple imputation via chained equations, controlling for within- person correlation across time (MD-1, MD-2, MD-3). We do not present analyses on these measures, as it was determined that while the matching process produced well-balanced measures for patient healthcare utilization, it was insufficient in producing comparable samples for each individual vital measurement. Finally, for the survey analysis, we report only raw results, with no hypothesis testing. We feel that this is more appropriate than reporting re-weighted raw counts, adjusting for survey response rates. If we were to conduct hypothesis testing, we would certainly account for both survey non-response as well as item • non-response (MD-1, MD-2).

• **5: Standards for Heterogeneity of Treatment Effects**	• We have attempted to break out CRS activities by clinic whenever it is scientifically meaningful, as we expect the largest source of heterogeneity to come from the different implementations of the CRS roll at different clinics (HT-1, HT2). Further break-down often ran into issues with sample size. We investigated whether our data could be used to provide • results stratified by age and gender, but ultimately decided that the small cell sizes were more
•	• likely to produce spurious findings than to identify subgroups where the CRS was particularly effective. (This is a conservative approach, as in general, we do not see large effects of the CRS on our outcome measures. As this decision was made before the analytic phase, no such • interaction analyses were performed.)
• **6: Standards for** • **Data Registries**	• Not applicable. Our study was an exploratory implementation study. It was not a • study to develop and analyze data from a patient registry
• **7: Standards for Data Networks as Research-Facilitating** • **Structures**	• Not applicable. Our study was an exploratory implementation study. It was not a study focused on developing or using data networks.

• **8: Standards for Causal Inference Methods**	• We attempted to produce analyses of utilization data that rule out potential sources of confounding. For analysis of healthcare utilization, our study design is a matched interrupted time series design with both pre- and post- periods for CRS patients and their controls (CI-1, CI-2, CI-3, CI-4). We are not aware of any changes in intervention or control clinics that would confound our results; our contact with clinical staff and leadership helped us • come to this conclusion.
• **9: Standards for Adaptive and Bayesian Trial • Designs**	• Not applicable. Our study was an exploratory implementation study. It was not a study that included an adaptive or Bayesian Trial Design
• **10: Standards for Studies of • Diagnostic Tests**	• Not applicable. Our study was an exploratory implementation study. It was not a study that included studies of any diagnostic tests.
11: Standards for Systematic Reviews	Not applicable. Our study was an exploratory implementation study. It was not a study that included a systematic review of the literature.